

REMARKS

Without acquiescing to the propriety of the rejections in the Office Action dated May 2, 2011, claims 1-3, 5, 9-10, 13, 19-20, 28-29, 33-34, 36-37, 39-40, and 43-44 have been amended, claims 8 and 31 have been cancelled, and new claim 84 has been added. Entry of these amendments, reconsideration of the present patent application and allowance of all claims pending herein are respectfully requested in view of the remarks below. Claims 38 and 71-83 were previously withdrawn, and claims 4, 6-7, 11-12, 14-18, 21-27, 30, 32, 35, 41-42 and 45-70 were previously cancelled. Claims 1-3, 5, 9-10, 13, 19-20, 28-29, 33-34, 36-37, 39-40, 43-44 and 84 are now pending and under consideration.

Claim Rejections Under 35 U.S.C. §102

Claims 1-3, 5, 8 and 19 are rejected as being anticipated by Stone et al. (US 5,306,311) (hereinafter referred to as "Stone").

The Office Action has rejected claims 1-3, 5, 8 and 19 alleging that Stone discloses the same invention being a cone shaped porous bioabsorbable plug implant comprising first and second circular planar portions having a tapered surface and a bioactive agent shown best in Figure 4B of Stone (reproduced below).

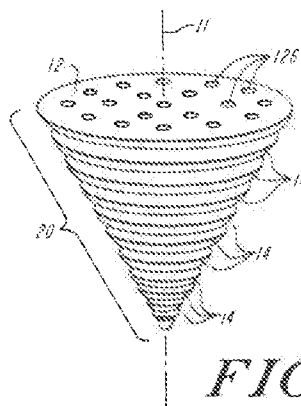


FIG. 4B

U.S. Patent No. 5,306,311 to Stone et al.

The Office Action further alleges that claim 1 only requires an implant having 2 portions having areas wherein one area is larger than the other and that due to its tapered form, there are numerous lower portions with smaller areas than the numerous upper portions.

Amended claim 1 recites, *inter alia*, a cranioplasty implant suitable for cranial bone tissue regeneration. Support for these amendments is found at least at paragraphs [0063], [0069] and [0081]. Accordingly, the remaining pending claims have also been amended to recite a cranioplasty implant. Amended claim 1 also recites that the first portion has a thickness X and the second portion has a thickness Y, and that the ratio X:Y is from 1:1 to 3:1. Support for the amendment is found at least at paragraphs [0072] and [0078]. New claim 84 recites a ratio X:Y as being from 2.75:1 to 3:1. Support for the new claim is found at least at paragraphs [0072] and [0078].

Applicant submits that the cranioplasty implant of claim 1 is not disclosed in Stone. In particular, column 5, lines 38 to 40 discloses that the prosthetic articular cartilage device disclosed in Stone is for joints having articulating surfaces. Further, Stone discloses at least at column 1, lines 23 to 31 and column 2, lines 50 to 54 that such prosthetic articular cartilage devices are used in load-bearing applications, such as a device for use in the knee joint. There is no disclosure in Stone of any non-load bearing applications of the device such as in cranioplasty. In fact, the device disclosed in Stone cannot be used for cranioplasty applications. In contrast, amended claim 1 specifically requires the implant to be a cranioplasty implant.

Amended claim 1 also requires the ratio of the thickness of the first portion to the thickness of the second portion of the cranioplasty implant to be from 1:1 to 3:1. There is no such thickness ratio disclosed in Stone in respect of the device disclosed in Stone.

Accordingly, because all the features (e.g. a cranioplasty implant suitable for cranial bone tissue regeneration, and a thickness ratio of the first portion to the second portion of from 1:1 to 3:1) of claim 1 of the present application are not identically disclosed by Stone, this claim cannot be anticipated thereby. The dependent claims are believed to not be anticipated for the same reasons and for their own additional features.

Claim Rejections Under 35 U.S.C. §103

Claims 9, 10, 13, 20, 28, 29, 31, 33, 34, 36, 37, 39, 40, 43, and 44 are rejected as being unpatentable over Stone in view of Masters (US 2002/0028243 A1) (hereinafter referred to as “Masters”).

As explained above, Stone teaches a load-bearing implant, in particular a prosthetic articular cartilage device, with specific application to the knee joint. A person of ordinary skill in the art intending to arrive at an improved cranioplasty implant would, therefore, not be motivated to refer to the teachings of Stone because the characteristics of a load-bearing implant as opposed to a non-load bearing implant as used in cranioplasty would be very different. Therefore, a person of ordinary skill in the art would understand that the prosthetic articular cartilage device as taught in Stone would not be suitable for cranioplasty application, as is required by amended claim 1. Accordingly, Stone would not be considered as being analogous prior art in the field of cranioplasty implants. Further, there would be no reasonable expectation of success in arriving at the claimed invention from combining Stone with Masters given the features lacking in Stone as described above.

Moreover, applicant submits that the cranioplasty implant as claimed in amended claim 1 is suitable for cranioplasty because the implant has a suitable ratio of the thickness of the first portion to the thickness of the second portion, while not requiring any means of attachment when the cranioplasty implant is inserted into a defect of a cranial bone. The ratio of the thickness of the first portion to the thickness of the second portion is important for cranial application. In particular, the first portion of the cranioplasty implant is inserted into the cranial bone defect while the second portion engages with the contour of the defect, thus avoiding the cranioplasty implant to penetrate into the cranial cavity, as explained at least at paragraphs [0075] and [0081] of the present application. Further, the larger and thinner second portion of the cranioplasty implant ensures that the cranioplasty implant remains in the contoured position of the defect of the cranial bone and is not pushed too far below the thickness of the cranium. A person of ordinary skill in the art referring to the device as taught in Stone would not have considered making such modifications based on the thickness of the device to arrive at the cranioplasty implant as claimed in amended claim 1 because

Stone only teaches devices used in load-bearing applications, which would require a different thickness ratio compared to cranioplasty.

Further, since the cranioplasty implant as recited in amended claim 1 is made of expandable material, the cranioplasty implant may be used without requiring means for attachment (e.g., screws). In particular, the expandable material in combination with the ratio of the thickness of the first portion to the thickness of the second portion of the cranioplasty implant allows the implant to “snap fit” into the defect or gap in the cranial bone, thus allowing an easy placement of the cranioplasty implant into the defect in the cranial bone in the shortest possible time as explained at paragraphs [0079] to [0081] of the present application.

Masters does not rectify the deficiencies of Stone as there is no teaching in Masters of a cranioplasty implant, let alone a cranioplasty implant having a first portion of thickness X and a second portion of thickness Y, wherein the ratio X:Y is from 1:1 to 3:1. Masters is more concerned with the teaching of materials suitable for various medical devices but is silent on the mechanical structure of these devices. Accordingly, even if the teachings of Stone and Masters are combined, a person of ordinary skill in the art would be unable to arrive at a cranioplasty implant having the advantages provided by the cranioplasty implant of amended claim 1.

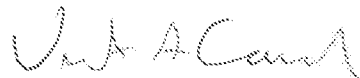
Accordingly, Applicant submits that the cranioplasty implant as recited in amended claim 1, and its dependent claims, are believed to be allowable over Stone in view of Masters.

CONCLUSION

It is believed that the application is on condition for allowance, and such action is respectfully requested.

If a telephone conference would be of assistance in advancing prosecution of the subject application, the Examiner is invited to telephone the undersigned attorney at the telephone number provided.

Respectfully submitted,



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